

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of )

James D. Marks et al. )

Serial No.: 09/250,056 )

Filed: February 12, 1999 )

For: INTERNALIZING ErbB2 )  
ANTIBODIES )

San Francisco, California

Assistant Commissioner of Patents  
Washington, D.C. 20231

DECLARATION CLAIMING SMALL ENTITY STATUS -  
SMALL BUSINESS CONCERN

Sir:

I, Linda S. Stevenson, hereby declare as follows:

I am Principal Prosecution Analyst of The Regents of the University of California, located at 1111 Franklin Street, 12<sup>th</sup> Floor, Oakland, CA 94607-5200 ("the Company").

The Company qualifies as a Small Business Concern, under the definition given below, for the purpose of paying reduced fees to the United States Patent and Trademark Office in connection with the prosecution and maintenance of the above-identified patent application. Exclusive rights to the invention of the above-identified patent application have been conveyed to and remain with the Company.

By "Small Business Concern" is meant any business concern (1) meeting the size standards set forth in 13 CFR Part 121, and (2) which has not assigned, granted, conveyed, or

licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an Independent Inventor if that person had made the invention, or to any concern which would not qualify as a Small Business Concern or a Nonprofit Organization. Concerns are "Affiliates" of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both. The number of employees of the business concern is the average over the fiscal year of the persons employed during each of the pay periods of the fiscal year. Employees are those persons employed on a full-time, part-time or temporary basis during the previous fiscal year of the concern.

By "Independent Inventor" is meant any inventor who (1) has not assigned, granted, conveyed, or licensed, and (2) is under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not likewise be classified as an Independent Inventor if that person had made the invention, or to any concern which would not qualify as a Small Business Concern or a Nonprofit Organization.

By "Nonprofit Organization" is meant any of the following:

- (1) a university or other institution of higher education located in any country; or
- (2) an organization of the type described in Section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S. 501(c)(3)) and exempt from taxation under Section 501(a) of the Internal Revenue Code (26 U.S. 501(a)); or
- (3) any nonprofit scientific or educational organization qualified under a nonprofit organization statute of a state of this country (35 U.S.C. 201(i)); or

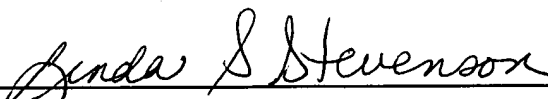
(4) any nonprofit organization located in a foreign country which would qualify as a nonprofit organization under sub-paragraphs (2) or (3) immediately above if it were located in this country.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize validity of the application, any patent issuing thereon, or any patent to which this statement is directed.

Date: June 1, 1999

(Atty. Docket: 2500.116US3)

  
\_\_\_\_\_  
Linda S. Stevenson



**PATENT APPLICATION DECLARATION**

(Attorney's Docket No.: 2500.116US3)

Each of the Applicants named below hereby declares as follows:

1. My residence, post office address and country of citizenship given below are true and correct.
2. I believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought in the patent application entitled "INTERNALIZING ErbB2 ANTIBODIES," Serial No. 09/250,056, filed February 12, 1999, and I have reviewed and understand the contents of the specification, including its claims.
3. I acknowledge my duty to disclose to the Office all information known to me to be material to patentability of this application, in accordance with 37 C.F.R. Section 1.56, which is defined on the attached page.
4. This application claims priority from U.S. provisional application Serial Number 60/082,953 filed April 24, 1998. I acknowledge my duty to disclose information of which I am aware which is material to the examination of this application, as defined in §1.56, which occurred between the filing date of the prior application and the filing date of this application.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 5/20/99

Residence and  
Post Office Address: James D. Marks  
107 Ardmore Road  
Kensington, CA 94707  
(Citizenship: USA)

Date: \_\_\_\_\_

Residence and Post Office Address: Marie Alix Poul  
165 Peralta Avenue, #5,  
San Francisco, CA 94110  
(Citizenship: France)

### **Section 1.56 Duty to Disclose Information Material to Patentability.**

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

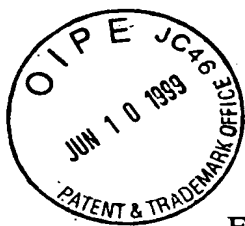
(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.



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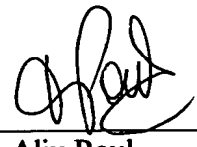
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Date: \_\_\_\_\_

James D. Marks  
Residence and 107 Ardmore Road  
Post Office Address: Kensington, CA 94707  
(Citizenship: USA)

Date: 31<sup>st</sup> May 1999



Residence and Post Office Address: Marie Alix Poul  
165 Peralta Avenue, #5,  
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